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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,700	NAKAZAWA ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

35 USC § 112, 6th Paragraph

1. With regard to Applicant's "means for pressure reduction means for reducing a residual pressure" of claims 6 and 7,

along with:

"adaptor means for delivering waste fluid;"

"clamped means ... for ... connection;"

"holding means for communicating and ... receiving;" and

"air discharge means for permitting" of claim 26,

the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

In the instant case, Examiner considers the button 88 and strap 90 of Rygiel (US Patent 4,397,643) to be an equivalent to the "pressure reduction means for reducing a residual pressure" disclosed by applicant, since it performs the same function (opening a receptacle) in the same way (increasing a volume of the interior space of said receptacle), with the same result (reducing a residual pressure) as the device disclosed by Applicant. For example, the immediate specification discloses opening cover body 15, which increases an interior volume of receptacle 600 and reduces residual pressure (p. 25, ¶ 5). Additionally, the button 88 and strap 90 of Rygiel is the structural equivalent of the tongue portion 15e and engagement pawl 23 as depicted on Fig. 1 of the drawing sheets. See MPEP 2183.

2. Regarding claims 6 and 7, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification. Examiner finds support in the immediate specification on: p. 5, ¶ 6; p.25, ¶ 5; and p.26, ¶ 4.

3. Regarding claim 26, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification. Examiner finds support in the immediate specification for:

"adaptor means for delivering waste fluid" on p. 15, ¶ 2, connection adaptor 32;

"clamped means ... for ... connection" on p. 15, ¶ 3, clamped portion 32d;

"holding means for communicating and ... receiving" on p. 15, ¶ 4, joining adaptor 33; and

"air discharge means for permitting" on p. 15, ¶ 5, check valve 34.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 20, 22, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Oikarinen et al. (WO 0149344).

6. Regarding claims 1, 3, 4, 20 and 23, Oikarinen discloses a receptacle for use with a medical suction device (p. 3, lines 14-19, Fig. 4, disposable suction bag 3);

[1, 23] which is equipped with a rigid case for detachably holding and air-tightly surrounding at least a portion of said receptacle (p. 3, lines 14-19, Fig. 4, airtight container 2). Oikarinen is silent regarding airtight container 2 being rigid. However, Examiner notes that a container 2 is necessarily rigid since during use, it maintains a negative pressure relative to atmospheric pressure.

[1, 23] Oikarinen further discloses a patient-side tube for introducing waste liquid into said receptacle (p. 3, lines 21-24, Fig. 4, tube (not shown) connected to suction bag 3);

[1, 23] designed to create a negative pressure in both an interior space of said rigid case and an interior space of said receptacle so as to allow waste liquid to be sucked into said receptacle through said patient-side tube (p. 3, lines 14-19, suction inlet 4 for producing underpressure in container 2 and bag 3);

[1] said receptacle comprising:

[1, 23] one port portion or connection adapter connected to said patient-side tube (p. 3, lines 21-24, Fig. 4, tube (not shown) connected to first lead-through means 6);

[1] a receptacle main body for holding waste fluid sucked through the port portion (Fig. 4, body of bag 3); and

[1] an air-pervious/liquid-impervious element having air perviousness and liquid imperviousness (p.3, lines 24-29, Fig. 4, filter 5);

[1] said air-pervious/liquid-impervious being provided in at least the portion of said receptacle main body (p.3, lines 24-29, Fig. 4, filter 5 provided on body of bag 3);

[1] wherein said air-pervious/liquid-impervious element is adapted to discharge air in the interior space of said receptacle to the interior space of said rigid case in response to the negative pressure created in the interior space of said rigid case (Fig. 4, space shown between second lead-through means 7 comprising filter 5 and suction inlet 4);

[1, 23] an outer peripheral portion of said port portion is detachably and air-tightly attachable to said rigid case, so that an entire region except for a part of said port portion is surrounded by said rigid case (p.4, lines 17-28, especially lines 26-28, Fig. 4, first lead-through means 6 extending through clamp 11); and

[23] a guide hole (Fig. 4, lumen extending through first lead-through means 6);

[3] wherein said air-pervious/liquid-impervious element is located below a connection position with said patient-side tube in the state after being held by said rigid case (Fig. 4, filter 5 depicted as below top end of first lead-through means 6);

[4] wherein said air-pervious/liquid-impervious element is located at a position corresponding to a liquid level for a target suction volume of waste liquid, in the state after being held by said rigid case (Fig. 4, filter 5 depicted near top of bag 3);

[20, 24] wherein the one port portion is the only port portion providing communication between the receptacle main body and areas external of the rigid case (Fig. 4, first lead-through means 6 providing only communication between interior of bag 3 and outer side of container 2). During use, suction inlet 4 is used to create underpressure within container 2 and bag 3 (p. 3, lines 14-19) and therefore does not provide communication between the main body of bag 3 and areas external of container 2. Additionally, Applicant provides an example of tube K2 (application drawings, Fig. 3) exiting a rigid case, which is not interpreted as providing communication between the receptacle main body and areas external of the rigid case.

7. Regarding claim 22, Oikarinen discloses a receptacle wherein:

the port portion includes an internal portion disposed adjacent an internal surface of the rigid case, an external portion disposed adjacent an external surface of the rigid case (Fig. 4, portions of first lead-through means 6 extending inside and outside of container 2), and

a clamp portion between the internal and external portions of the port portion and configured for air tight engagement with areas of the rigid case between the internal and external surfaces thereof (p. 4, lines 17-28, especially lines 18-23, Fig. 4, clamp 11).

8. Regarding claim 26, Oikarinen discloses the invention as substantially claimed, including:

connection adaptor means for delivering waste fluid sucked through the patient-side tube to the interior space of the rigid case (Fig. 4, first lead-through means 6);

clamped means on the connection adaptor means for detachable air-tight connection to the rigid case (Fig. 4, portion of first lead-through means 6 extending through clamp 11); and

waste fluid holding means for communicating with the connection adaptor means and for receiving the waste fluid delivered to the interior space of the rigid case by the connection adaptor means (Fig. 4, body of bag 3); and

air discharge means for permitting a flow of air from an interior space of the waste fluid holding means to the interior space of the rigid case and for preventing a flow of the waste fluid from the interior space of the waste fluid holding means to the interior space of the rigid case external of the waste holding means (Fig. 4, filter 5 provided on body of bag 3).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Olson (US Patent 5,275,585).

12. Regarding claim 2, Oikarinen discloses the invention substantially as claimed, see above. However, Oikarinen lacks a check valve as claimed [claim 2]. Olson discloses a receptacle and rigid case for medical suction (col. 2, lines 47-52, col. 3, lines 15-30, Fig. 1, autotransfusion system 10 comprising collection bag 26 and rigid receptacle 16). Olson further discloses:

a check valve adapted to allow waste liquid sucked from said patient-side tube to flow into the interior space thereof (col. 3, lines 51-64, especially lines 57-59, Figs. 4-5, suction port 46 and exhaust port 48 both comprising one-way valves not depicted); and

prevent said sucked waste liquid from flowing out to said patient-side tube (it is the Examiner's position that check valves limit backwards flow from collection bag 26 within rigid receptacle 16 as depicted).

Olson provides the advantage of retaining liquid within a collection receptacle, and preventing fluid from refluxing to a patient. One would be motivated to modify Oikarinen with the check valve as taught by Olson to prevent reflux since both blood and medical waste fluids are sources of contamination and need to be securely contained. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen as discussed with the check valve as taught by Olson in order to retain medical wastes within a container and prevent reflux.

13. Claims 6, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Keogh; Alan P. et al. (US 5669892).

14. Regarding claims 6 and 7, Oikarinen discloses the invention substantially as claimed, see above. However, Oikarinen lacks pressure reduction means as claimed [claims 6 and 7]. Keogh discloses a suction drainage system that prevents overfill (col. 2, lines 9-16) comprising a rigid container and receptacle (col. 3, lines 14-28, Fig. 1, rigid container 12 and collection chamber 20). Keogh further discloses:

[6] a pressure reduction means for reducing a residual pressure in the interior space thereof after completion of the waste-liquid collecting operation (col. 4, lines 1-23, especially lines 12-17, Fig. 2, overfill protection sleeve 40); and

[7] pressure reduction means that is adapted to increase a volume of the interior space of said receptacle so as to reduce said residual pressure (col. 4, lines 24-34,

additional clearance of sleeve 40 providing "give" during capping and removal of chamber 20).

Keogh provides the advantage of preventing spilling or geysering (col. 1, lines 47-54). One would be motivated to modify Oikarinen with the additional volume as taught by Keogh to prevent overfill since medical wastes need to be stored securely and are generally hazardous. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen as discussed with the pressure reduction means as taught by Keogh in order to prevent overfill and leaks when emptying a fluid collection device.

15. Regarding claim 12, Oikarinen discloses the invention substantially as claimed, see above. However, Oikarinen lacks a coagulating agent as claimed [claim 12]. Keogh discloses a receptacle that includes a coagulating agent adapted to coagulate a collected waste liquid (col. 1, lines 55-64, col. 3, lines 56-67, especially lines 65-67, gelling agent). Keogh provides the advantage of containing medical waste in a gelled form that is less likely to spill. One would be motivated to modify Oikarinen with the coagulating agent as taught by Keogh to prevent spilling since gelled waste is a more stable form. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen as discussed with the coagulating agent as taught by Keogh in order to prevent spilling.

16. Claims 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Verkaart (US Patent 4,466,888).

17. Regarding claim 5, Oikarinen discloses the invention as substantially claimed, including an air-pervious/liquid-impervious element (Fig. 4, filter 5). However, Oikarinen arranges filter 5 differently than claimed [claim 5]. Verkaart discloses a blood collection assembly having a rigid outer case and inner flexible bag (col. 3, lines 48-52, 59-65; Figs. 1-3, shells 20 and 22 and collection bag 30) further comprising:

an air- pervious/liquid-impervious element located over a given range below said liquid level for the target suction volume of waste liquid, in the state after being held by said rigid case (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 located over range extending below a liquid level for the target suction volume of liquid when held within shells 20 and 22). Verkaart provides the advantage of removing foam from collected blood (col. 5, lines 19-28). This is relevant to the problem of collecting and disposing of blood, since foamed blood may harbor pathogens that will pass into a suction pump or vacuum line. In other words, the air- pervious/liquid-impervious element of Verkaart prevents pathogens from exiting a collection bag as foam.

18. Regarding claims 8 and 9, Olson discloses the invention as substantially claimed, see above. However, Olson lacks a second sheet and rigid port portion as claimed [claims 8 and 9]. Verkaart discloses a receptacle main body that includes:

[8, 9] a first sheet having air-imperviousness and liquid-imperviousness (cols. 3-4, lines 59-65, 65-3, Fig. 4, bag made of PVC and having plastic faces); and

[8] a second sheet including said air-pervious/liquid impervious element and having a peripheral edge joined to a peripheral edge of said first sheet (col. 5, lines 3-

36, especially lines 9-14, 33-36; Fig. 4, filter 70 sealed to peripheral edges of plastic bag faces); and

[8, 9] a port portion that is rigid and joined between said first and second sheets and adapted to form a part of a passage for introducing waste liquid between said first and second sheets (col. 6, lines 51-64; Fig. 8, inlet fitting 110 and filter screen 100 heat sealed between front and rear bag faces as depicted); and

[8, 9] said receptacle is designed to allow said first and second sheets to be entirely surrounded by said rigid case while air-tightly attaching an outer peripheral surface of said port portion to said rigid case (cols. 3-4, lines 67-9; Figs. 1-3, bag 30 placed within front and rear shells 20 and 22);

[9] a second sheet having air-perviousness and liquid-imperviousness to serve as said air-pervious/liquid-impervious element, said second sheet having a peripheral edge joined to a peripheral edge of said first sheet (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 sealed to peripheral edges of plastic bag faces);

Regarding the limitation of a second sheet including an air-pervious/liquid-impervious element, Examiner interprets the blockage of foamed liquid as being substantially liquid-impervious. Filter 70 of Verkaart is interpreted as the second sheet of both claims 8 and 9, since no additional structure is claimed. To clarify, filter 70 of Verkaart is interpreted as a second sheet for both claims 8 and 9, since the claims do not depend on each other. Verkaart provides the advantage of preventing aspirated liquid from leaving a collection receptacle. Oikarinen calls for preventing fluid from exiting a collection receptacle with a filter (p. 6, lines 6-10, filter 5 acting closes when

moistened, to act as an overfill protector and cork). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen as discussed with the fastening element as taught by Manica in order to store active agents separately, and prolong their shelf life.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Bormann et al. (US Patent Application Publication No. 2002/0029021).

20. Regarding claim 10, Oikarinen discloses the invention as substantially claimed, including:

a bag-shaped sheet having air-imperviousness and liquid-imperviousness (p. 3, lines 14-19, Fig. 4, bag 3 requiring second lead-through means 7 to pass air, and therefore being substantially air-impervious); and

a sheet adapted to collect waste liquid in an interior space thereof (Fig. 4, bag 3 adapted to collect liquid). However, Oikarinen lacks a communication member as claimed [claim 10]. Bormann discloses a device for transferring fluid (¶ [0021], [0022], [0033], Fig. 4, device 100), further comprising a communication member for forming a passage (¶ [0033], Fig. 9, housing 14 comprising porous medium 10);

which provides fluid communication between the interior and exterior spaces of a chamber (Fig. 4, porous medium 10 dividing interior and exterior portions of housing 14 as depicted);

wherein an air- pervious/liquid- impervious element is incorporated in said communication member in such a manner as to close said passage (¶ [0046]-[0048], porous medium 10 preventing overfilling when wetted by rising liquid level).

Bormann provides the advantage of closing a collection system based on a rising fluid level, which prevents overfilling (¶ [0046]-[0048], porous medium 10 preventing overfilling when wetted by rising liquid level). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson as discussed with the communication member as taught by Bormann in order to prevent overfilling.

Regarding the limitation of bag-shaped sheet as claimed [claim 10], Examiner notes that no additional structure is being claimed. To clarify, bag 3 of Oikarinen is interpreted as the bag-shaped sheet of claim 10, and porous medium 10 of Bormann is interpreted as the communication member of claim 10.

Examiner notes that claim 10 has been amended to require that the communication member be part of a receptacle main body. Although Bormann discloses a communication member as part of a rigid housing, the same advantage applies to incorporating a communication member in a flexible sheet or rigid housing. Additionally, the limitation of a communication member between spaces of a sheet can be practiced by layering a porous or spongy member between impermeable materials.

21. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Verkaart (US Patent 4,466,888), further in view of Manica et al. (US Patent Application Publication No. 2002/0138066).

22. Regarding claim 11, Oikarinen in view of Verkaart discloses the invention as substantially claimed, see above. However, Oikarinen in view of Verkaart lacks a fastening element as claimed [claim 11]. Manica discloses a receptacle which further includes:

a fastening element for fastening a folded portion of said sheet to prevent said folded portion from being unfolded (¶ [0066], [0067], Figs. 15, 16, removable clamp 710);

said fastening element being designed to release the fastened state of said folded portion in response to expansion of said receptacle which is caused by a difference between a pressure in a space located inside said rigid case and outside said receptacle and a pressure in the interior space of said receptacle (¶ [0069], Figs. 15, 16, removable clamp 710 removed to combine fluids within separate chambers of container 700);

occurring in an initial stage of the creation of a negative pressure in the interior space of said rigid case (Examiner notes that clamp 710 may be removed at an initial stage).

Manica provides the advantage of storing active agents separately during storage (end of ¶ [0068], compartments aiding in oxidation reactions after removal of clamp 710). In other words, storing agents separately allows a longer storage life, since

the reactants are held in an unmixed, unreacted state. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen in view of Verkaart as discussed with the fastening element as taught by Manica in order to store active agents separately, and prolong their shelf life.

23. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Keogh; Alan P. et al. (US 5669892), further in view of Manica et al. (US Patent Application Publication No. 2002/0138066).

24. Regarding claim 13, Oikarinen in view of Keogh discloses the invention as substantially claimed, see above. However, Oikarinen in view of Keogh lacks a partition portion as claimed [claim 13]. Manica discloses a system for decontaminating blood or blood components with a pathogen inactivation agent (¶ [0003], [0004], [0013]), further comprising:

a partition portion for partitioning the interior space of said receptacle into a waste-liquid receiving chamber for collecting waste liquid therein (¶ [0056], Fig. 3, removable seal assembly 35); and

an agent storage chamber for storing said agent (¶ [0056], [0058], Fig. 3, sub-compartment 14 for storing solution A);

said partition portion being adapted to provide fluid communication between said waste-liquid receiving chamber and said coagulating- agent storage chamber according to a given operation of a user (¶ [0058], Fig. 3, providing fluid communication between

sub-compartments 12 and 14 through removing removable seal assembly 35). Manica provides the advantage of quickly combining blood with an active agent. Additionally, Manica provides the advantage of separating a caregiver from blood-borne pathogens since the mixing step does not involve opening a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson in view of Keogh as discussed with the partition portion as taught by Manica in order to quickly add an active agent while protecting a caregiver.

Manica solves the problem of storing blood and inactivating pathogens. While Manica discloses anticoagulant solution stored within a chamber instead of the claimed coagulant, this provides the same advantage of treating blood during collection. In this rejection, Keogh teaches an example of coagulant, and Manica teaches an example of a partition portion. Examiner notes that the claims are drawn to structures of a receptacle, not the specific contents of a receptacle.

25. Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oikarinen et al. (WO 0149344) in view of Manica et al. (US Patent Application Publication No. 2002/0138066).

26. Regarding claims 21 and 25, Oikarinen discloses the invention substantially as claimed, including an outer peripheral portion that is dimensioned to provide air-tightness with a rigid case (p. 1, lines 1-8, p. 5, lines 25-31, a peripheral portion of first lead-through means 6 sealing inside clamp 11). However, Oikarinen is silent regarding the material of first lead-through means 6, and therefore lacks a synthetic resin as

claimed [claims 21 and 25]. Manica discloses a port portion that is made of a synthetic resin having elasticity (¶ [0039], [0041], Fig. 3, portions of tubing assemblies made of PVC and ports or openings 21, 22). PVC has a long history of being used to form storage containers for medical liquid due to its low cost, flexibility and biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Oikarinen as discussed with the PVC as taught by Manica in order to select a material with desirable properties.

Response to Arguments

27. Applicant's arguments, see p. 9-12 filed 30 January 2009 with respect to the rejection(s) of claim(s) 1-13 under 35 USC § 102 and 103 over Olson, Rygiel, Manica, Borman and Verkart have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 102 and 103 over Oikarinen, Keogh, Olson, Manica, Borman and Verkart.

28. Applicant asserts that Olson lacks a port portion that is detachable, since the blood inlet tube 20 is not detachably attached to either the rigid receptacle 16 or the lid 18 that is permanently affixed to the rigid receptacle 16. Applicant reasons that nothing in Olson suggests the significant re-design that would be required to bring Olson closer to the invention defined by amended claim 1. Applicant also notes that none of the secondary references teach or suggest a receptacle with a port portion and a receptacle

main body where an outer peripheral portion of the port portion is detachably an air-tightly attachable to rigid case of a medical suction device. Examiner notes that Oikarinen teaches a detachable port portion in the new grounds of rejection. Oikarinen has also been applied as a primary reference to new claims 20-26.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Deaton; David W. US 4379455
- Ferguson; Keith et al. US 5306264
- Villefrance; Tine US 6506184

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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